Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

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Report Date:11/17/2008

Study Summary

Laboratory Name	Study Number	Study Start Date	Length of Study in Days	Number of Animals Total and (#/Cage)	Number Surviving and (Mean Life Span)	Maximum Mean Weekly Body Weight	Chemical	
				Ma	ale			
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 059902303 059902005	04/22/02 03/25/02 04/09/03	729 729 727	50 (3) 50 (3) 50 (3)	35(702) 29(683) 39(685)	521.9 501.9 514.9	Isoeugenol beta-Myrcene Pulegone	
				Fen	nale			
Battelle Columbus Laboratory Battelle Columbus Laboratory Battelle Columbus Laboratory	058810503 059902303 059902005	04/23/02 03/26/02 04/10/03	730 730 728	50 (5) 50 (5) 50 (5)	33(699) 31(668) 31(682)	339.3 323.8 341.2	Isoeugenol beta-Myrcene Pulegone	

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Contract/Lab: All Laboratories Species: RATS

Strain: F344 Length of Study: CHRONIC Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#All Organs: Benign Tumors		49/50 (98%)	40/50 (000()	47/50 (94%)		41/50 (82%)	40/50 (80%)	42/50 (84%)
Overall Incidence	Total	145/150 (96.67%)	49/50 (98%) Mean 96.67%	SD 2.31%	Total	123/150 (82%)	Mean 82%	42/50 (84%) SD 2%
#All Organs: Malignant Tumors		20/50 (50%)	00/50 (400/)	40/50 (20%)		40/50 (20%)	44/50 (000()	0/50 /400/)
Overall Incidence	Total	29/50 (58%) 62/150 (41.33%)	23/50 (46%) Mean 41.33%	10/50 (20%) SD 19.43%	Total	18/50 (36%) 37/150 (24.67%)	11/50 (22%) Mean 24.67%	8/50 (16%) SD 10.26%
#All Organs: Malignant and Benign To	umors	F0/50 (400%)	50/50 (400%)	47/50 (04%)		40/50 (000/)	45/50 (00%)	44/50 (000)
Overall Incidence	Total	50/50 (100%) 147/150 (98%)	50/50 (100%) Mean 98%	47/50 (94%) SD 3.46%	Total	46/50 (92%) 135/150 (90%)	45/50 (90%) Mean 90%	44/50 (88%) SD 2%
#All Organs: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
#All Organs: Hemangiosarcoma		1/50 (39/)	0/50 (09/)	0/50 (0%)		0/50 (09/)	0/50 (09/)	2/50 (49/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%
#All Organs: Hemangiosarcoma or He	emangioma	4/50 (004)		0/50 (00/)		0/50 (00/)	4/50 (004)	0/50 (40/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 3/150 (2%)	1/50 (2%) Mean 2%	2/50 (4%) SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#All Organs: Histiocytic Sarcoma		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Leukemia: Erythrocytic	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Leukemia: Lymphocytic, Undifferentiated	Monocytic, M	lononuclear, or						
verall Incidence	Total	10/50 (20%) 23/150 (15.33%)	9/50 (18%) Mean 15.33%	4/50 (8%) SD 6.43%	Total	8/50 (16%) 17/150 (11.33%)	5/50 (10%) Mean 11.33%	4/50 (8%) SD 4.16%
All Organs: Malignant Lymphoma: Hi or Undifferentiated Cell T	stiocytic, Lyn							
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
All Organs: Mesothelioma: Benign		0/50 (00)	0/50 (00)			0/50 (00/)	0/50 (004)	0/50 (00)
Mesothenoma. Beingn		0/50 (0%)	0/50 (0%)	0/50 (0%)	.	0/50 (0%)	0/50 (0%)	0/50 (0%)
•	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Overall Incidence						0/150 (0%)		

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

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Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 7

			Male				Female	
All Organs: Mesothelioma: Malignant								
	-	3/50 (6%)	2/50 (4%)	2/50 (4%)	-	0/50 (0%)	1/50 (2%)	1/50 (2%)
Overall Incidence	Total	7/150 (4.67%)	Mean 4.67%	SD 1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%
All Organs: Osteoma		2/22	2(22)	0.50		2/22 (221)	2(-2)	2/22 (221)
verall Incidence	Total	0/50 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
veran incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Iolai	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma								
	-	2/50 (4%)	1/50 (2%)	0/50 (0%)	+	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
All Organs: Osteosarcoma or Osteoma								
	Tatal	2/50 (4%)	1/50 (2%)	0/50 (0%)	Tatal	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
drenal Cortex: Adenoma								
		0/50 (0%)	1/50 (2%)	2/50 (4%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	0/150 (0%)	Mean 0%	SD 0%
Adrenal Cortex: Carcinoma		0/50 /00/	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)	T-1-1	0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

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Report Date:11/17/2008

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
*Adrenal Medulla: Ganglioneuroma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Adrenal Medulla: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Adrenal Medulla: Pheochromocytoma Benign		5/50 (10%)	11/50 (22%)	8/50 (16%)		2/50 (4%)	1/50 (20/)	2/50 (69/)
Overall Incidence	Total	5/50 (10%) 24/150 (16%)	Mean 16%	SD 6%	Total	2/50 (4%) 6/150 (4%)	1/50 (2%) Mean 4%	3/50 (6%) SD 2%
*Adrenal Medulla: Pheochromocytoma Complex	×	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Adrenal Medulla: Pheochromocytoma Malignal	nt	(004)		0/20 (00)		(0)	(0.0)	(00)
Overall Incidence	Total	3/50 (6%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	0/50 (0%) SD 3.06%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Adrenal Medulla: Pheochromocytoma: Benign	, Complex	x, Malignant, NOS 7/50 (14%)	13/50 (26%)	8/50 (16%)		2/50 (4%)	1/50 (2%)	3/50 (6%)
Overall Incidence	Total	28/150 (18.67%)	Mean 18.67%	SD 6.43%	Total	6/150 (4%)	Mean 4%	SD 2%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Bone: Chondrosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chondrosarcoma or Cho	ondroma		0/50 (00/)		•••••			
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Chordoma		0/50 (00/)			•••••			
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Bone: Osteosarcoma	•••••	0/50 (40/)	4/50 (00)	0/50 (00/)	•••••	0/50 (00/)	0/50 (00()	0/50 (00/)
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Bone: Osteosarcoma or Osteor	na		(204)		•••••			
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	1/50 (2%) Mean 2%	0/50 (0%) SD 2%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 10

			Male	Female
Brain: Astrocytoma Malignant		0/50 (0%)	0/50 (0%) 1/50 (2%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
Brain: Ependymoma Benign		0/50 (0%)	1/50 (2%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
Brain: Ependymoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Brain: Glioma Malignant	•••••	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Brain: Granular Cell Tumor Benign		0/50 (00/)	0/50 (00)	0/50 (00) 0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%
Brain: Medulloblastoma Mal		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%)	Mean 0% SD 0%	Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Contract/Lab: All Laboratories Species: RATS

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 11

			Male				Female	
Brain:								
Meningioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Meningioma: Benign, Maligr	ant. NOS				•••••			
	,	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain:								
Oligodendroglioma Benign						- 4		
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Brain: Oligodendroglioma Maligna								
Oligodendi oglionia Malignai	ıı	1/50 (2%)	0/50 (0%)	0/50 (0%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
overall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Brain:								
Oligodendroglioma, Glioma,	or Astroc	vtoma						
g	/	1/50 (2%)	1/50 (2%)	1/50 (2%)		1/50 (2%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Brain: Osteosarcoma					•••••			(00)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

			Male	Female
*Brain: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
*Clitoral/Preputial Gland: Adenoma				
Overall Incidence	Total	2/50 (4%) 10/150 (6.67%)	5/50 (10%) 3/50 (6%) Mean 6.67% SD 3.06%	3/48 (6%) 7/50 (14%) 3/50 (6%) Total 13/148 (8.78%) Mean 8.75% SD 4.55%
*Clitoral/Preputial Gland: Carcinoma				
Overall Incidence	Total	2/50 (4%) 3/150 (2%)	0/50 (0%) 1/50 (2%) Mean 2% SD 2%	2/48 (4%) 0/50 (0%) 0/50 (0%) Total 2/148 (1.35%) Mean 1.39% SD 2.41%
*Clitoral/Preputial Gland: Carcinoma or Adenoma		4/50 (8%)	5/50 (10%) 4/50 (8%)	5/48 (10%) 7/50 (14%) 3/50 (6%)
Overall Incidence	Total	13/150 (8.67%)	Mean 8.67% SD 1.15%	Total 15/148 (10.14%) Mean 10.14% SD 4.01%
Clitoral/Preputial Gland: Fibrosarcoma				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/48 (0%) 0/50 (0%) 0/50 (0%) Total 0/148 (0%) Mean 0% SD 0%
*Clitoral/Preputial Gland: Sarcoma				0/40 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/48 (0%) 0/50 (0%) 0/50 (0%) Total 0/148 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
*Clitoral/Preputial Gland: Squamous Cell Papilloma		0/50 (00/)	0/50 (0%)	0/50 (0%)		0/49 (00/)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/48 (0%) 0/148 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Ear: Neural Crest Tumor		0/50 (00/)	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Fibrosarcoma		0/50 /00()	0/50 (00/)	0/50 (00)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Esophagus: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Eye: Amelanotic Melanoma, Ber	nign	0/50 (00/)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Eye: Melanoma Benign								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 14

			Male				Female	
#Eye: Melanoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Eye: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Harderian Gland: Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Heart: Schwannoma Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
*Heart: Schwannoma Malignant		0/50 (00/)	0/50 (00)	0/50 (00/)		0/50 (00)		0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female	
#Intestine Large: Colon/Rectum Adenoma	1:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Carcinoma	n:	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Carcinoma or Adenoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Large: Colon/Rectum Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Intestine Small: Duodenum: Carcinoma		- ()		- / / / / / / / / / /				
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Intestine Small: Duodenum: Leiomyoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

			Male	Female
Intestine Small: Jejunum: Carcinoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
Intestine Small: Jejunum: Granular Cell Tumor Malignan				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Jejunum: Leiomyoma				
		1/50 (2%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
	Total	1/150 (0.67%)	Mean 0.67% SD 1.15%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Jejunum: Leiomyosarcoma				0/50 (00/) 0/50 (00/) 0/50 (00/)
verell Incidence	Total	` ,	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/450 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Site Unspecified Carcinoma	:			
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%
ntestine Small: Site Unspecified Carcinoma or Adenoma				
		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%) Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Report Date:11/17/2008

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Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male		Total 0/150 (0%) Mean 0% (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) Mean 0% (0%) 0/50 (0%) 0/50 (0%)							
Overall Incidence	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` ,	0/50 (0%) SD 0%				
#Intestine Small: Site Unspec Leiomyoma	cified:	(20)	(00)	(201)	•••••	(201)	(004)	(00)				
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	` '	` ,	0/50 (0%) SD 0%				
#Intestine Small: Site Unspec Leiomyosarcoma	cified:			(201)	•••••							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` '	` ,	0/50 (0%) SD 0%				
*Islets, Pancreatic: Adenoma		4/50 (8%)	2/50 (4%)	2/50 (4%)	•••••	0/50 (0%)	1/50 (29/)	1/50 (2%)				
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 2.31%	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%				
*Islets, Pancreatic: Carcinoma		0/50 (00/)	4/50 (20()	0/50 (0%)		0/50 (00/)	0/50 (0%)	0/50 (/0//)				
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%				
*Islets, Pancreatic: Carcinoma or Adenoma		4/50 (00()	0/50 (00/)	0/50 /40/)		0/50 (00/)	4/50 (00/)	4/50 (00)				
Overall Incidence	Total	4/50 (8%) 9/150 (6%)	3/50 (6%) Mean 6%	2/50 (4%) SD 2%	Total	0/50 (0%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	1/50 (2%) SD 1.15%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

			Male				Female					
*Kidney: Pelvis and Transitional Epithelium: Carcinoma												
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
(idney: Pelvis and Transition Carcinoma or Adenoma	al Epitheliur											
		0/50 (0%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Pelvis and Transition Papilloma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Renal Tubule: Adenoma						•••••						
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
rerall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Renal Tubule: Carcinoma												
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
rerall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%				
idney: Renal Tubule: Carcinoma or Adenoma		(00)	2/22 (22)	(00)		(00)	(0)	(20)				
		0/50 (0%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	0/50 (0%)				
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%				

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data

Species: RATS Strain: F344

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 19

			Male		Female
Kidney: Renal Tubule: Hemangiosarcoma					
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
Kidney: Renal Tubule: Lipoma		0/50 (00/)	4/50 (001)	0/50 (00)	0/50 (001)
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
verall illefaction	Total	1/130 (0.07/0)	Weat 0.07/6 3D 1.13/6	Total 0/130 (070)	Weati 076
Kidney: Renal Tubule: Liposarcoma		0/50 (00()	2/52 (221)	0/50 (00)	0/50 (001)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
verali ilicidence		, ,	Weatt 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
(idney: Renal Tubule: Mesenchymal Tumor Benign		0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
				•••••	
Kidney: Renal Tubule: Nephroblastoma					
warali laaidanaa	Total	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	1/50 (2%) 0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 1/150 (0.67%)	Mean 0.67% SD 1.15%
Cidney: Renal Tubule: Sarcoma		0/50 (00()	0/50 (00/) 0/50 (00/)	0/50 (00)	0/50 (00/) 0/50 (00/)
Verall Incidence	Total	0/50 (0%)	0/50 (0%) 0/50 (0%)	0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

31011.11012000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 20

			Male				Female	
Liver: Cholangioma		27-2 (22)		2(52 (22))		2/52 (221)	(201)	
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
.iver: Hemangiosarcoma		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/30 (0%)	Mean 0%	0/50 (0%) SD 0%
.iver: Hepatocellular Adenoma		1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
iver: Hepatocellular Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
iver: Hepatocellular Carcinoma o	or Hepatob		0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
iver: Hepatocellular Carcinoma o	or Hepatoc	ellular Adenoma 1/50 (2%)	0/50 (0%)	1/50 (2%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Page: 21 Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
*Liver: Hepatocellular Carcinon Hepatoblastoma	na, Hepatocell	ular Adenoma, or						
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
*Lung:		•••••	•••••					
Alveolar/Bronchiolar Ad	enoma	3/50 (6%)	3/50 (6%)	0/50 (0%)		1/50 (2%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	6/150 (4%)	Mean 4%	SD 3.46%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%
*Lung: Alveolar/Bronchiolar Ca	rcinoma							
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Lung: Alveolar/Bronchiolar Ca Adenoma	rcinoma or Al	veolar/Bronchiolar 4/50 (8%)	3/50 (6%)	1/50 (2%)		1/50 (2%)	4/50 (8%)	2/50 (4%)
Overall Incidence	Total	8/150 (5.33%)	Mean 5.33%	SD 3.06%	Total	7/150 (4.67%)	Mean 4.67%	SD 3.06%
*Lung: Hemangiosarcoma			•••••		•••••		•••••	•••••
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Lung: Sarcoma								
Garconia		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

Vehicle: CORN OIL

Route: GAVAGE

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Report Date: 11/17/2008

Length of Study: CHRONIC

Male Female *Lung: **Squamous Cell Carcinoma** 0/50 (0%)0/50 (0%)0/50 (0%)(0%)1/50 (2%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 1/150 (0.67%) Mean 0.67% SD 1.15% **#Lymph Node:** Hemangiosarcoma 0/50 (0%)(0%)0/50 (0%)0/50 0/50 0/50 (0%)0/50 (0%)**Overall Incidence** SD 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%)Mean 0% **#Lymph Node, Mesenteric:** Sarcoma 0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% SD 0% #Mammary Gland: Adenoma (0%)(0%)0/50 (0%)(0%)(0%)2/50 (4%)0/50 0/50 0/50 0/50 2/150 (1.33%) **Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total Mean 1.33% SD 2.31% #Mammary Gland: Carcinoma 0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%)(0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% Total 4/150 (2.67%) Mean 2.67% SD 4.62% #Mammary Gland: Carcinoma or Adenoma 0/50 (0%)0/50 (0%)0/50 (0%)4/50 (8%)0/50 (0%)2/50 (4%)**Overall Incidence** 0/150 (0%) SD 0% SD 4% Total Mean 0% Total 6/150 (4%) Mean 4%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 23

			Male				Female	
Mammary Gland: Fibroadenoma								
		4/50 (8%)	0/50 (0%)	1/50 (2%)		26/50 (52%)	17/50 (34%)	21/50 (42%)
verall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	Total	64/150 (42.67%)	Mean 42.67%	SD 9.02%
Mammary Gland: Fibroma								
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Mammary Gland: Fibroma, Fibroadenon								
		4/50 (8%)	0/50 (0%)	1/50 (2%)		26/50 (52%)	17/50 (34%)	22/50 (44%)
verall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	Total	65/150 (43.33%)	Mean 43.33%	SD 9.02%
Mammary Gland: Fibroma, Fibroadenom		or Adenoma						
	T	4/50 (8%)	0/50 (0%)	1/50 (2%)	.	28/50 (56%)	17/50 (34%)	22/50 (44%)
verall Incidence	Total	5/150 (3.33%)	Mean 3.33%	SD 4.16%	Total	67/150 (44.67%)	Mean 44.67%	SD 11.02%
Mesentery: Fibrosarcoma		0(50 (00))	0.750 (001)	(00)		2/52 (224)	2(20)	(201)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
lesentery: Hemangiosarcoma			0.70			(004)	(00)	(00)
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Species: RATS Strain: F344

Length of Study: CHRONIC

Route: GAVAGE Vehicle: CORN OIL

			Male				Female	
#Mesentery: Lipoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Mesentery: Rhabdomyosarcoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Adenoma		0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (0%)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Nose: Chondroma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Nose: Squamous Cell Carcinoma	·····	0/50 (00/)	0/50 (00/)	(00)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Oral Cavity (Oral Mucosa, To Papilloma Squamous or P	ngue, Phary	nx, Tooth, Gingiva):						
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

				Ma	ale					Female	
Oral Cavity (Oral Mucosa, Tong Squamous Cell Carcinoma	ue, Phary	nx, Tooth,	Gingiva):								
1		1/50	(2%)	0/50	(0%)	0/50	(0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
	•••••										
Oral Cavity (Oral Mucosa, Tong Squamous Cell Carcinoma, F Papilloma											
		1/50	(2%)		(2%)	0/50	(0%)		0/50 (0%)	2/50 (4%)	0/50 (0%)
verall Incidence	Total		(1.33%)		1.33%		1.15%	Total	2/150 (1.33%)	Mean 1.33%	SD 2.31%
Oral Mucosa: Squamous Cell Carcinoma										4/50 (004)	
		1/50	(2%)		(0%)	0/50	(0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	1/150	(0.67%)	Mean	0.67%	SD	1.15%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Oral Mucosa: Squamous Cell Papilloma		0/50	(0%)	1/50	(2%)	0/50	(0%)		0/50 (0%)	0/50 (09/)	0/50 (0%)
verall Incidence	Total		(0.67%)		0.67%		1.15%	Total	0/150 (0%)	0/50 (0%) Mean 0%	SD 0%
Ovary: Granulosa Cell Tumor Benig	n							Tatal	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence								Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Ovary: Granulosa Cell Tumor Maligi	nant								0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence								Total	` ,	0/50 (0%) Mean 0%	` '
verali incidence								Total	0/150 (0%)	wean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 26

Report Date: 11/17/2008

Route: GAVAGE
Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

Male Female *Ovary: Granulosa Cell Tumor: Benign, Malignant, NOS 1/50 (2%)(0%)**Overall Incidence** Total 1/150 (0.67%) Mean 0.67% SD 1.15% **Granulosa-Theca Tumor Benign** 0/50 0/50 0/50 (0%)**Overall Incidence** SD 0% Total 0/150 Mean 0% *Ovary: **Granulosa-Theca Tumor Malignant** 0/50 (0%)0/50 (0%)0/50 (0%)**Overall Incidence** Total 0/150 (0%) Mean 0% SD 0% *Ovary: **Tubulostromal Adenoma** (0%)0/50 (0%)0/50 Mean 0% **Overall Incidence** Total 0/150 (0%) SD 0% *Pancreas: Adenoma 7/50 (14%)(2%)2/50 (4%)0/50 0/50 0/50 (0%)**Overall Incidence** Total 10/150 (6.67%)Mean 6.67% SD 6.43% Total 0/150 Mean 0% SD 0% *Pancreas: Carcinoma (2%)(0%)0/50 (0%)(0%)0/50 (0%)0/50 (0%)**Overall Incidence** SD 1.15% SD 0% Total 1/150 (0.67%) Mean 0.67% Total 0/150 (0%) Mean 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 27

			Male				Female	
*Pancreas: Carcinoma or Adenoma								
Overall Incidence	Total	8/50 (16%) 11/150 (7.33%)	1/50 (2%) Mean 7.33%	2/50 (4%) SD 7.57%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Pancreas: Mixed Tumor Benign		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Pancreas: Mixed Tumor Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Parathyroid Gland: Adenoma		0/47 (00()	4/45 (00)	4/40 (00)		0/47 (00/)	0/47 (00/)	0/40 /40/)
Overall Incidence	Total	0/47 (0%) 2/141 (1.42%)	1/45 (2%) Mean 1.42%	1/49 (2%) SD 1.23%	Total	0/47 (0%) 2/140 (1.43%)	0/47 (0%) Mean 1.45%	2/46 (4%) SD 2.51%
#Peripheral Nerve: Schwannoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Peripheral Nerve: Schwannoma: Benign, Mali	ignant, NOS							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for S

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 28

			Male				Female	
Pituitary Gland: Pars Distalis o Adenoma	or Unspecif	fied Site:						
		19/50 (38%)	6/50 (12%)	11/50 (22%)		25/50 (50%)	25/50 (50%)	27/50 (54%)
verall Incidence	Total	36/150 (24%)	Mean 24%	SD 13.11%	Total	77/150 (51.33%)	Mean 51.33%	SD 2.31%
Pituitary Gland: Pars Distalis o Carcinoma	or Unspecif							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Distalis o Carcinoma or Adenoma								
		19/50 (38%)	6/50 (12%)	11/50 (22%)		25/50 (50%)	25/50 (50%)	27/50 (54%)
verall Incidence	Total	36/150 (24%)	Mean 24%	SD 13.11%	Total	77/150 (51.33%)	Mean 51.33%	SD 2.31%
Pituitary Gland: Pars Intermed Adenoma								
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Intermed Carcinoma	ia:							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Pituitary Gland: Pars Intermed Carcinoma or Adenoma	ia:	4/50 (00()	0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 /00/
		1/50 (2%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

SIUII. NUVZUUO

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 29

			Male	Male Female			(0%) 0% (0%) 0% (0%) 0% (0%) 0/49 (0%) 0/50 (0%) (0%) 0/49 (0%) 0/50 (0%)		
*Prostate: Adenoma		0/50 (00/)	0/50 (09/)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
*Prostate: Carcinoma or Adenoma		0/50 (00()	0/50 (0%)	0/50 (00/)					
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
*Salivary Glands: Sarcoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	` ,	` ,	0/50 (0%) SD 0%	
*Salivary Glands: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/49 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	` ,	` ,	SD 0%	
#Seminal Vesicle: Adenoma									
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%					
#Skeletal Muscle: Hemangioma		0/50 (00()	0/50 (0%)	0/50 (0%)		0/50 (00/)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

131011: 11012000

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 30

			Male				Female	
#Skeletal Muscle: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Lipoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	Mean 0%	0/50 (0%) SD 0%	Total	0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma								
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Rhabdomyosarcoma or R	habdomyom							
verall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skeletal Muscle: Sarcoma								
overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
Skin: Basal Cell Adenoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 31

	Male						Female	
#Skin:								
Basal Cell Adenoma or	Basosquamou							
		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin:								
Basal Cell Adenoma, Ba	asosquamous ⁻	Tumor Benign, or						
Trichoepithelioma		0/50 (0%)	0/50 (00/)	0/50 (00/)		0/50 (00/)	1/FO (20/)	0/50 (00/)
	-	` ,	0/50 (0%)	0/50 (0%)	-	0/50 (0%)	1/50 (2%)	0/50 (0%)
verall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
					•••••			
Skin:								
Basal Cell Carcinoma		1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
	T-1-1	` ,	` '	` '	T-1-1	` ,	` '	` '
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Basal Cell Carcinoma o NOS)	r Basosquamo	ous Tumor (malignant o	or 1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
verall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin:								
Basal Cell Carcinoma, E								
		Trichoepithelioma						
Basal Cell Carcinoma, E Tumor (benign, maligna	ant or NOS), or	Trichoepithelioma 1/50 (2%)	1/50 (2%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)
Basal Cell Carcinoma, E Tumor (benign, maligna		Trichoepithelioma		0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%
Basal Cell Carcinoma, E Tumor (benign, maligna verall Incidence	ant or NOS), or Total	Trichoepithelioma 1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	SD 1.15%		1/150 (0.67%)	Mean 0.67%	SD 1.15%
Basal Cell Carcinoma, E Tumor (benign, maligna overall Incidence Skin: Basal or Sq. Cell Carcin or B), Basal Cell Adeno	Total Toma, Carcinon ma, Adenoma,	Trichoepithelioma 1/50 (2%) 2/150 (1.33%) ma, Basosq. Tumor (M Papilloma, Sq	1/50 (2%) Mean 1.33%	SD 1.15%		1/150 (0.67%)	Mean 0.67%	SD 1.15%
Tumor (benign, maligna Overall Incidence Skin: Basal or Sq. Cell Carcin	Total Toma, Carcinon ma, Adenoma,	Trichoepithelioma 1/50 (2%) 2/150 (1.33%) ma, Basosq. Tumor (M Papilloma, Sq	1/50 (2%) Mean 1.33%	SD 1.15%		1/150 (0.67%)	Mean 0.67%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 32

Report Date:11/17/2008

	Male					Female			
#Skin: Fibroma									
Overall Incidence	Total	5/50 (10%) 11/150 (7.33%)	3/50 (6%) Mean 7.33%	3/50 (6%) SD 2.31%	Total	0/50 (0%) 5/150 (3.33%)	2/50 (4%) Mean 3.33%	3/50 (6%) SD 3.06%	
	ı olul								
Skin: Fibroma, Fibrosarcoma, S Fibrous Histiocytoma	Sarcoma, My	xoma, Myxosarcoma, or							
·		7/50 (14%)	4/50 (8%)	3/50 (6%)		0/50 (0%)	3/50 (6%)	3/50 (6%)	
Overall Incidence	Total	14/150 (9.33%)	Mean 9.33%	SD 4.16%	Total	6/150 (4%)	Mean 4%	SD 3.46%	
Skin: Fibrosarcoma		(150 (00))	0/50 (00/)	0/50 (00/)		0/50 (00)	4/50 (00/)	0/50 (00/)	
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
	rotai	17100 (0.0770)	Widaii 0.0770	05 1.1070		17100 (0.0770)	Wicaii 0.0770	05 1.1070	
Skin: Fibrosarcoma, Sarcoma, Histiocytoma	Myxosarcom	,							
Nucual Incidence	Total	2/50 (4%)	1/50 (2%)	0/50 (0%)	Total	0/50 (0%)	1/50 (2%)	0/50 (0%)	
verall Incidence	Total	3/150 (2%)	Mean 2%	SD 2%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
Skin: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Hemangioma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/30 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
	· Otal	3, . 33 (070)		G2 070	· Otal	0, 100 (070)		32 370	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 33

			Male				Female	
#Skin: Hemangiosarcoma								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Keratoacanthoma		7/50 (440/)	2/50 /40/\	2/50 (69/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	7/50 (14%) 12/150 (8%)	2/50 (4%) Mean 8%	3/50 (6%) SD 5.29%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Lipoma	•••••							
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Liposarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Skin: Neural Crest Tumor		0/50 (/0//)	0/50 /00/	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Skin: Neural Crest Tumor, Mali	ignant							
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Contract/Lab: All Laboratories

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Page: 34

Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

	Male					Female			
∜Skin: Neurofibroma or Schwar	nnoma benign	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
Skin: Neurofibrosarcoma or So		malignant or NOS)			•••••	•••••			
verall Incidence	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skin: Neurofibrosarcoma, Neu malignant or NOS)	rofibroma, or	, ,							
Overall Incidence	Total	0/50 (0%) 3/150 (2%)	0/50 (0%) Mean 2%	3/50 (6%) SD 3.46%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skin: Osteosarcoma	•••••	0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (09/)	
verall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skin: Sarcoma	•••••								
Overall Incidence	Total	1/50 (2%) 2/150 (1.33%)	1/50 (2%) Mean 1.33%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
Skin: Schwannoma Benign		0/50 (00/)	0/50 (00/)	0/50 (0%)		0/50 (0%)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 35

			Male				Female	
∜Skin: Schwannoma Malignant		0/50 (0%)	0/50 (0%)	3/50 (6%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	3/150 (2%)	Mean 2%	SD 3.46%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcino		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Carcino Basosquamous Tumor (1/50 (2%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	2/150 (1.33%)	Mean 1.33%	SD 1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Skin: Squamous Cell Papillom	na	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Skin: Squamous Cell Papillom	na or Papillom	a 0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)
	Tatal	0/30 (0%)	0/50 (0%) Mean 0%	0/30 (0%) SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%
Overall Incidence	Total	0/130 (070)				` ,		
Overall Incidence #Skin: Squamous Cell Papillom Carcinoma or Keratoaca	na, Papilloma,		2/50 (4%)			0/50 (0%)	0/50 (0%)	1/50 (2%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 36

				Ma	ale					Female	
Skin: Squamous Cell Papilloma,	Papilloma, o			- 1			()				
verall Incidence	Total	7/50 12/150	(14%) (8%)	2/50 Mean	(4%) 8%	3/50 SD	(6%) 5.29%	Total	0/50 (0% 1/150 (0.67%	, , ,	1/50 (2%) SD 1.15%
verali ilicidence			,						,	•	
Skin: Trichoepithelioma											
verall Incidence	Total	0/50 0/150	(0%) (0%)	0/50 Mean	(0%)	0/50	(0%) 0%	Total	0/50 (0% 0/150 (0%)	0) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
			` ,						(
Skin: Sebaceous Gland: Adenoma)	
	.	1/50	(2%)	1/50	(2%)	0/50	(0%)	.	0/50 (0%	, , ,	0/50 (0%)
verall Incidence	Total	2/150	,		1.33%	_	1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
kin: Sebaceous Gland: Carcinoma	••••••										
verall Incidence	Total	0/50 0/150	(0%) (0%)	0/50 Mean	(0%) 0%	0/50 SD	(0%) 0%	Total	0/50 (0% 0/150 (0%)	0) 0/50 (0%) Mean 0%	0/50 (0%) SD 0%
refail illeluefice	Total	0/130	(070)	Mean	0 70	SD	0 70	iotai	0/130 (070)	Weatt 070	3D 070
ikin: Sebaceous Gland: Carcinoma or Adenoma											
		1/50	(2%)		(2%)	0/50	(0%)		0/50 (0%	, , ,	0/50 (0%)
verall Incidence	Total	2/150	(1.33%)	Mean	1.33%	SD	1.15%	Total	0/150 (0%)	Mean 0%	SD 0%
Spinal Cord: Astrocytoma Benign											
warall Incidence	Total	0/50	(0%)		(0%)	0/50	(0%)	Total	0/50 (0%	, , ,	0/50 (0%)
verall Incidence	Total	0/150	(0%)	Mean	υ%	SD	0%	Total	1/150 (0.67%	Mean 0.67%	SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS
Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 37

			Male				Female	
#Spinal Cord: Astrocytoma Malignant								
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Spinal Cord: Glioma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
*Spleen: Fibrosarcoma		0/50 (00/)	0/50 (00/)			0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Fibrous Histiocytoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
*Spleen: Hemangioma		0/50 /00/	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Spleen: Hemangiosarcoma		4/50 (00)	0/50 (00/)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (40/)
Overall Incidence	Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	2/50 (4%) SD 2.31%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS Strain: F344

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 38

		Male				Female	
	0(50 (00/)	0/50 (00)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0(50 (00))
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
	0/50 (00/)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (00/)	0/50 (00/)
Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
		•••••					
	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
or Papillon	na Squamous						
Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
				•••••			
Total	0/50 (0%) 0/150 (0%)	0/50 (0%)	0/50 (0%) SD 0%	Tatal	` '	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
	Total Total or Papillon Total	0/50 (0%) Total 0/150 (0%) 0/50 (0%) Total 0/150 (0%) Total 0/150 (0%) or Papilloma Squamous 0/50 (0%) Total 0/150 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) Mean 0% 0/50 (0%) 0/50 (0%)	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total O/150 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%)	Total 0/50 (0%) 0/50 (0%) 0/50 (0%) D/50 (0%) Nean 0% SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Total 0/50 (0%) 0/50 (0%) Nean 0% 0/50 (0%) SD 0% Total 0/50 (0%) 0/50 (0%) 0/50 (0%) Nean 0% 0/50 (0%) Nean 0% 0/50 (0%) SD 0% Total 0/50 (0%) 0/50 (0%) Nean 0% 0/50 (0%) Nean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Nean 0% 0/50 (0%) Nean 0% SD 0% Total 0/50 (0%) 0/50 (0%) Nean 0% 0/50 (0%) Nean 0% SD 0% Total	O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) O/50 (0%) Total	Total 0/50 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) Mean 0% Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0% Total 0/150 (0%) 0/50 (0%) 0/50 (0%) Total 0/150 (0%) 0/50 (0%) 0/50 (0%)

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories

Species: RATS

Length of Study: CHRONIC

Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL Page: 39

	Male					Female		
#Stomach, Glandular: Leiomyosarcoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/30 (0%)	Mean 0%	SD 0%
#Stomach, Glandular: Lipoma		0/50 (00/)	0/50 (0%)	0/50 (00/)		0/50 (00)	0/50 (00/)	0/50 (00)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
*Testes: Adenoma		46/50 (020/)	47/50 (049/)	46/EQ (020/)				
Overall Incidence	Total	46/50 (92%) 139/150 (92.67%)	47/50 (94%) Mean 92.67%	46/50 (92%) SD 1.15%				
*Thymus: Sarcoma		0/47 (00/)	2/47 (22/)	0/50 (00/)	•••••	0/47 (00)	0/40 (00/)	0/50 (00)
Overall Incidence	Total	0/47 (0%) 0/144 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%
*Thymus: Thymoma Benign		0/47 (0%)	0/47 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
Overall Incidence	Total	0/144 (0%)	Mean 0%	SD 0%	Total	0/146 (0%)	Mean 0%	SD 0%
*Thymus: Thymoma Malignant		0/47 (00/)	0/47 (00/)	0/50 (00/)		0/47 (00/)	0/40 (00/)	0/50 /00/
Overall Incidence	Total	0/47 (0%) 0/144 (0%)	0/47 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/47 (0%) 0/146 (0%)	0/49 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Page: 40 Report Date:11/17/2008

Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

**Thymona: Benign, Malignant, NOS Overall Incidence Total O/144 (0%) Overall Incidence Total O/145 (0%) Overall Incidence Total O/146 (0%) Overall Incidence O/148 (0%) Overall Incidence O/150 (18%) Overall Incidence O/150 (18%) Overall Incidence Total O/150 (0%) Overall Incidence O/150 (12%) Overall Incidence O/150 (0%) Overall I		Male						Female	
Overall Incidence Total 0/144 (0%) Mean 0% SD 0% Total 0/146 (0%) Mean 0% SD 0% "Thyroid Gland: C-Cell: Adenoma 9/50 (18%) 12/50 (24%) 8/50 (16%) 7/50 (14%) 5/50 (10%) 8/50 (16%) Overall Incidence Total 29/50 (18.33%) Mean 19.33% SD 4.16% Total 20/150 (13.33%) Mean 13.33% SD 3.06% "Thyroid Gland: C-Cell: Carcinoma 6/50 (12%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (16%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) <t< th=""><th></th><th>nt, NOS</th><th>0/47 (0%)</th><th>0/47 (0%)</th><th>0/50 (0%)</th><th></th><th>0/47 (0%)</th><th>0/49 (0%)</th><th>0/50 (0%)</th></t<>		nt, NOS	0/47 (0%)	0/47 (0%)	0/50 (0%)		0/47 (0%)	0/49 (0%)	0/50 (0%)
Adenoma	Overall Incidence	Total	` ,	()	` ,	Total	` '	` '	` /
Overall Incidence Total 29/150 (19.33%) Mean 19.33% SD 4.16% Total 20/150 (13.33%) Mean 13.33% SD 3.06% *Thyroid Gland: C-Cell: Carcinoma 6/50 (12%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) *Thyroid Gland: C-Cell: Carcinoma or Adenoma 15/50 (30%) 12/50 (24%) 8/50 (16%) 9/50 (18%) 5/50 (10%) 8/50 (10%) 8/50 (16%) *Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% Total 22/150 (14.67%) Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50 (0%) 1/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%)			0/50 (400/)	40/50 (04%)	0/50 (400/)		7/50 (4.40())	5/50 (400)	0/50 (400/)
Carcinoma Coroll Coroll Coroll Carcinoma	Overall Incidence	Total	` ,	` ,	, ,	Total	,	` ,	` '
Overall Incidence Total 6/150 (4%) Mean 4% SD 6.93% Total 3/150 (2%) Mean 2% SD 3.46% *Thyroid Gland: C-Cell: Carcinoma or Adenoma 15/50 (30%) 12/50 (24%) 8/50 (16%) 9/50 (18%) 5/50 (10%) 8/50 (16%) Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% Total 22/150 (14.67%) Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50			0/50 (40%)	0/50 (00/)	0/50 (00/)		0/50 (00/)	0/50 (0%)	0/50 (00/)
Carcinoma or Adenoma 15/50 (30%) 12/50 (24%) 8/50 (16%) Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 7.02% Total 2/150 (14.67%) Mean 14.67% Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 1/50 (2%) 0/50 (0%) Mean 1.33% SD 1.15% Total 0/150 (0%) 0/50 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 1/50 (2%) 0/50 (0%) O/50 (0%) Total 0/150 (0%) Mean 0% SD 0%	Overall Incidence	Total	` ,	` ,	` ,	Total	` '	` '	` /
Overall Incidence Total 35/150 (23.33%) Mean 23.33% SD 7.02% Total 22/150 (14.67%) Mean 14.67% SD 4.16% *Thyroid Gland: Follicular Cell: Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) </td <td></td> <td></td> <td>15/50 (30%)</td> <td>12/50 (24%)</td> <td>9/50 (169/)</td> <td></td> <td>0/50 /199/\</td> <td>5/50 (10%)</td> <td>9/50 (169/.)</td>			15/50 (30%)	12/50 (24%)	9/50 (169/)		0/50 /199/\	5/50 (10%)	9/50 (169/.)
Adenoma 1/50 (2%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%) 0/50 (0%) Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%) 0/50 (0%) 0/50 (0%)	Overall Incidence	Total	` ,	` ,	, ,	Total	` ,	` ,	` '
Overall Incidence Total 2/150 (1.33%) Mean 1.33% SD 1.15% Total 0/150 (0%) Mean 0% SD 0% *Thyroid Gland: Follicular Cell: Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%) <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td> <td></td>									
Carcinoma 1/50 (2%) 2/50 (4%) 0/50 (0%) 1/50 (2%) 0/50 (0%)	Overall Incidence	Total	` '	` '	, ,	Total	` ,	` ,	` '
	•		4/50 (00/)	0/50 (40/)	0/50 (00/)		4/50 (00/)	0/50 (0%)	0/50 (00/)
	Overall Incidence	Total	, ,	` '	` ,	Total	(/	` '	` '

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Toxicology Data Management System

Contract/Lab: All Laboratories

Tumor Incidence for Selected Control Animal Groups

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Species: RATS Strain: F344 Route: GAVAGE Vehicle: CORN OIL

			Male		Female
*Thyroid Gland: Follicular Cell: Carcinoma or Adenoma					
Overall Incidence	Total	2/50 (4%) 5/150 (3.33%)	3/50 (6%) 0/50 (0%) Mean 3.33% SD 3.06%	,	0/50 (0%) 0/50 (0%) Mean 0.67% SD 1.15%
#Tissue NOS: Lipoma		0/50 (00/)	0/50 (00/) 0/50 (00	0/50 (00/)	0/50 /00/\ 0/50 /00/\
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tissue NOS: Paraganglioma		0/50 (09/)	0/50 (00/) 0/50 (00	0/50 (00/)	0/50 /00/\ 0/50 /00/\
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tissue NOS: Schwannoma Malignant		0/50 (0%)	0/50 (0%) 0/50 (0%	%) 0/50 (0%)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/30 (0%)	Mean 0% SD 0%	Total 0/150 (0%)	Mean 0% SD 0%
#Tongue: Squamous Cell Carcinoma		0/50 (00/)	0/50 (00) 0/50 (00)	N) 0/50 (00)	0/50 (0%) 0/50 (0%)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%
#Tongue: Squamous Cell Carcinoma of	or Papillon		0/50 (00/) 0/50 (00	O/FQ (20%)	4/50 (00/) 0/50 (00/)
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) 0/50 (0%) Mean 0% SD 0%	%) 0/50 (0%) Total 1/150 (0.67%)	1/50 (2%) 0/50 (0%) Mean 0.67% SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

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Report Date:11/17/2008

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

	Male					Female			
#Tongue: Squamous Cell Papilloma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	1/50 (2%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
#Tooth: Adamantinoma Malignant		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
#Tooth: Odontoma		0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	1/50 (2%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	1/150 (0.67%)	Mean 0.67%	SD 1.15%	
*Urinary Bladder: Carcinoma		0/50 (0%)	0/50 (0%)	0/50 (0%)	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%	
*Urinary Bladder: Carcinoma or Papilloma		(201)	(20)	(00)		(201)	(201)	(00)	
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
*Urinary Bladder: Leiomyosarcoma		0/50 (00/)	0/50 (00)	0/50 (00)	•••••	0/50 (00)	0/50 (00/)	0/50 (00/)	
Overall Incidence	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male					Female			
*Urinary Bladder: Papilloma									
Overall Incidence	Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Uterus: Adenoma									
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
#Uterus: Carcinoma	•••••								
Overall Incidence					Total	0/50 (0%) 1/150 (0.67%)	1/50 (2%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Uterus: Deciduoma Benign		•••••		•••••					
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%	
#Uterus: Hemangioma						0/50 (00/)	0/50 (00/)	0/50 (0%)	
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%	
	• • • • • • • • • • • • • • • • • • • •		•••••					•••••	
#Uterus: Hemangiosarcoma						0/50 (0%)	0/50 (0%)	0/50 (0%)	
Overall Incidence					Total	0/30 (0%)	Mean 0%	SD 0%	

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Tumor Incidence for Selected Control Animal Groups

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Report Date:11/17/2008

Route: GAVAGE

Vehicle: CORN OIL

Length of Study: CHRONIC

Contract/Lab: All Laboratories

	Male			Female	
#Uterus: Leiomyoma			2/22 (22/)		2/20 (201)
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Leiomyosarcoma					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Polyp Stromal		••••••			
Overall Incidence		Total	8/50 (16%) 21/150 (14%)	8/50 (16%) Mean 14%	5/50 (10%) SD 3.46%
#Uterus: Sarcoma Stromal					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Uterus: Sarcoma Stromal or Polyp Stromal		•••••			
Overall Incidence		Total	8/50 (16%) 21/150 (14%)	8/50 (16%) Mean 14%	5/50 (10%) SD 3.46%
#Uterus: Schwannoma Malignant					
Overall Incidence		Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied

Species: RATS

Strain: F344

Toxicology Data Management System

Contract/Lab: All Laboratories Tumor Incidence for Selected Control Animal Groups

Route: GAVAGE Vehicle: CORN OIL

Length of Study: CHRONIC

d Control Animal Groups Report Date:11/17/2008

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			Male				Female	
#Vagina: Polyp						1/50 (2%)	0/50 (0%)	0/50 (09/)
Overall Incidence					Total	1/50 (2%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	0/50 (0%) SD 1.15%
• • • • • • • • • • • • • • • • • • • •			•••••				•••••	•••••
#Vagina: Sarcoma								
Overall Incidence					Total	0/50 (0%) 0/150 (0%)	0/50 (0%) Mean 0%	0/50 (0%) SD 0%
#Zymbal's Gland: Adenoma	•••••	0/50 (0%)	0/50 (0%)	0/50 (0%)		0/50 (0%)	0/50 (0%)	0/50 (0%)
Overall Incidence	Total	0/150 (0%)	Mean 0%	SD 0%	Total	0/150 (0%)	Mean 0%	SD 0%
#Zymbal's Gland: Carcinoma		2/50 (4%)						
Overall Incidence	Total	2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%
#Zymbal's Gland: Carcinoma or Adenoma	•••••							
Overall Incidence	Total	2/50 (4%) 2/150 (1.33%)	0/50 (0%) Mean 1.33%	0/50 (0%) SD 2.31%	Total	0/50 (0%) 1/150 (0.67%)	0/50 (0%) Mean 0.67%	1/50 (2%) SD 1.15%

^{*:} Denominator is number of animals with tissues examined microscopically

^{#:} Denominator is number of animals necropsied